

### **DETAILED ACTION**

The response filed 4/26/2011 to the Office action has been entered. Claims 2, 6, 11-12, 15-21, 23-31 are pending.

1. Claims 2, 11-12, and 16-18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Laue et al. (7374883, issued May 20, 2008) in view of Lowe et al. (Nucleic acid research, 1990 Vol. 18(7)).

Laue et al. disclose a method for detecting Severe Acute Respiratory Syndrome-associated virus (SARS). A real time RT-PCR reaction is performed in which a forward primer binds to a region defined by nucleotides 69-98 of SEQ ID NO: 1 and a reverse primer binds to a region defined by nucleotides 123-168 of SEQ ID NO: 1 and a probe labeled with a fluorescent dye binds to a region defined by nucleotides 89-132 of SEQ ID NO: 1 for the detection (see column 2, lines 4-24). As indicated in the search report, the nucleotides 80 to 297 of SEQ ID NO: 1 comprises instant SEQ ID NOs: 3, 4, 7 (see the attached nucleic acid search report). SEQ ID NO: 4 of Laue et al. is 24 nucleotides in length and comprises the instant SEQ ID NO: 8 which is 21 nucleotides in length (see the attached nucleic acid sequence search report). SEQ ID NO: 4 of Laue et al. is used a probe for the detection (see column 6, lines 50-55). A PCR-derived construct comprises a promoter sequence for T7 RNA polymerase (see column 8, lines 2-7). The primers used in the method are 18-31 nucleotides in length (see column 2, lines 10-14).

Lowe et al. disclose a computer program for selecting oligonucleotide primers for PCR from a known sequence (pg. 1758, column 1) and the primer is specific and effective (see pg. 1757, the Abstract).

One of ordinary skill in the art would have been motivated to construct a pair of oligonucleotides within instant SEQ ID NOs: 3-4 and 7-8 for amplifying a target sequence of the genome of SARS Coronavirus with a reasonable expectation of success because Laue et al. disclose a method of detecting SARS with a pair of primers and a known sequence, and Lowe et al. disclose a computer program for selecting oligonucleotide primers for PCR from a known sequence (pg. 1758, column 1) and the primer is specific and effective (see pg. 1757, the Abstract). It would have been prima facie obvious to construct a pair of oligonucleotides within the instant SEQ ID NOs: 3-4 and 7-8 for amplifying a target sequence of the genome of SARS Coronavirus as claimed.

2. Claims 2 and 20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Briese et al. (20040265796, issued Dec. 30, 2004) in view of Lowe et al. (Nucleic acid research, 1990 Vol. 18(7)).

Briese et al. disclose a PCR and real time PCR assay for detecting the SARS-associated coronavirus. The assay allows for rapid molecular detection and has improved sensitivity and specificity (see [0008]). A kit for the detection is also provided. The kit comprises a primer set comprising at least two nucleic acid sequences (see [0014]). As indicated in the search report, SEQ ID NO: 1 comprises instant SEQ ID NOs: 25 and 29 which are recited in claims 2 and 8 (see pg. 10 and the search report). SEQ ID NO: 1 includes the 3' non-coding region of the SARS-associated coronavirus genome and a portion of the N gene of the SARS-associated coronavirus genome (see pg. 2, [0019]).

The teachings of Lowe et al. are set forth in section 1 above.

One of ordinary skill in the art would have been motivated to construct a pair of oligonucleotides within instant SEQ ID NOs: 25 and 29 for amplifying a target sequence located within the gene encoding the nucleocapsid protein of the genome of SARS Coronavirus with a reasonable expectation of success because Briese et al. disclose an assay of detecting SARS with a pair of primers from a known sequence, the assay allows for rapid molecular detection and has improved sensitivity and specificity (see [0008]) and Lowe et al. disclose a computer program for selecting oligonucleotide primers for PCR from a known sequence (pg. 1758, column 1) and the primer is specific and effective (see pg. 1757, the Abstract). It would have been prima facie obvious to construct a pair of oligonucleotides within SEQ ID NO: 25 and 29 for amplifying a target sequence located within the gene encoding the nucleocapsid protein of the genome of SARS Coronavirus as claimed.

3. Claim 15 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Laue et al. (7374883, issued May 20, 2008) in view of Lowe et al. (Nucleic acid research, 1990 Vol. 18(7)) as applied to claims 2, 4, 11-13, 16-18 and 22 above, and further in view of Tyagi et al. (Nature Biotechnology, 1996 Vol. 14, pg. 303-308).

The teachings of Laue et al. and Lowe et al. are set forth in section 1 above. Laue et al. and Lowe et al. do not disclose the limitations of claim 15.

Tyagi et al. disclose molecular beacon probes that recognize and report the presence of specific nucleic acids in homogeneous solutions (see pg. 303, the Abstract).

One of ordinary skill in the art would have been motivated to apply a molecular beacon probe for detection as taught by Tyagi et al. because the probe is sensitive and can be used in a

sealed tube (see pg. 303, the Abstract). It would have been prima facie obvious to apply a molecular beacon probe for detection.

4. Claims 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laue et al. (7374883, issued May 20, 2008) in view of Lowe et al. (Nucleic acid research, 1990 Vol. 18(7)) as applied to claims 2, 4, 11-13, 16-18 and 22 above, and further in view of Compton et al. (Nature, 1991, Vol. 350(7), pg. 912-992).

The teachings of Laue et al. and Lowe et al. are set forth in section 1 above. Laue et al. and Lowe et al. do not disclose the limitations of claims 19 and 21.

Compton discloses a standard NASBA reaction which comprises a first primer with a promoter sequence at 5' end for recognizing T7 RNA polymerase and reagents for the reaction (see pg. 91, column 1).

One of ordinary skill in the art would have been motivated to apply a NASBA reaction for detection SARS nucleic acid in a sample with a reasonable expectations of success because the NASBA process requires fewer cycles than PCR to produce a desired amplification (see pg. 91, column 3). In addition including reagents in a kit for a NASBA reaction would have been a routine practice for conveniently performing a reaction. It would have been prima facie obvious to carry out a NASBA reaction and to make a kit including a NASBA reagent for detecting SARS nucleic acid in a sample.

5. Claims 6, and 23-31 are free of prior art.
6. Regarding the response filed 4/26/11, it points that claims 2, 12 and 15 are amended to define the invention. However, the response does not provide evidences that these primer pairs for amplifying SARS CoV RNA work better than others. Thus, the rejection is maintained.
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOYCE TUNG whose telephone number is (571)272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Joyce Tung/  
Examiner, Art Unit 1637  
June 29, 2011

/Gary Benzion/  
Supervisory Patent Examiner, Art Unit 1637